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Andrew A. Paul 46,405  
Name of Attorney/Agent Registration No.  
Signature of Attorney or Agent

P&G Case 7989R

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :  
Stanislaw (NMN) Pikul et al. : Confirmation No.  
Serial No. : Group Art Unit 1626  
Filed January 16, 2004 : Examiner Robert W. Ramsuer

For **Heterocyclic Side Chain Containing, N-Substituted Metalloprotease Inhibitors**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made on the attached Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. ☒ 37 C.F.R. §1.97(b)(1) - U.S. Direct (use when filing IDS with nonprovisional patent application, or with Request for Continued Examination (RCE); or within 3 months of filing a nonprovisional patent application)

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(1), is being filed with the patent application, with a Request for Continued Examination or within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2. ☐ **37 C.F.R. §1.97(b)(3) - (use when filing IDS more than 3 months after filing a nonprovisional patent application, but prior to receipt of first Office Action)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

3. ☐ **37 C.F.R. §1.97(b)(4) - (use when filing IDS prior to receipt of first Office Action after the filing of a Request for Continued Examination (RCE) under §1.114)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(4). Applicants have not received a first Office Action after filing a Request For Continued Examination (RCE). Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

4. ☐ **37 C.F.R. §1.97(c) with fee payment - (use when filing IDS after receipt of first Office Action, and before receipt of Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter (or a fee transmittal form) is enclosed to facilitate the charging of the fee.

5. ☐ **Information to be Considered with Continued Prosecution Application (CPA) Filing (use when filing IDS with a Continued Prosecution Application (CPA) for Design Case)**. This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 C.F.R. 1.53(d).

**ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:**

☐ (1) (For use with applications filed prior to or on June 30, 2003.) Copies of the cited documents are enclosed.

OR

☒ (2) (For use with applications filed after June 30, 2003.) In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

OR

☒ (3) All of the cited references were previously cited by or submitted to the USPTO in prior application Case No. 7989R, U.S. Patent Application Serial No. 10/243,511, filed 9/13/2002. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

OR


☐ (4) Copies of all said documents, except Cite Numbers \_\_\_\_\_, were submitted and considered in parent application U.S. Patent Application Serial No. \_\_\_\_\_, filed \_\_\_\_\_. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of references not previously submitted are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

☐ (5) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

☐ (6) Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.

☐ Additional information is attached.

Respectfully submitted,

By 

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Date: January 16, 2004  
**Customer No. 27752**  
(IDS.doc) (Last Revised 10/10/03)

Please type a plus sign (+) inside this box → [+]

PTO/SB08A/B (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

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<p>Substitute for form 1449A/PTO</p> <h2 style="margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="margin: 0;">(use as many sheets as necessary)</p> <p style="margin-top: 20px;">SHEET 1 of 3</p>	<p><b>COMPLETE IF KNOWN</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Application Number</td> <td></td> </tr> <tr> <td>Confirmation Number</td> <td></td> </tr> <tr> <td>Filing Date</td> <td>January 16, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Stanislaw (NMN) Pikul</td> </tr> <tr> <td>Group Art Unit</td> <td>1626</td> </tr> <tr> <td>Examiner Name</td> <td>Robert W. Ramsuer</td> </tr> <tr> <td>Attorney Docket Number</td> <td>7989RD</td> </tr> </table>	Application Number		Confirmation Number		Filing Date	January 16, 2004	First Named Inventor	Stanislaw (NMN) Pikul	Group Art Unit	1626	Examiner Name	Robert W. Ramsuer	Attorney Docket Number	7989RD
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Group Art Unit	1626														
Examiner Name	Robert W. Ramsuer														
Attorney Docket Number	7989RD														

### U. S. PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	DOCUMENT NUMBER	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1	US- 4,743,587	05/10/1988	Dickens, et al.	
	2	US- 4,771,038	09/13/1988	Wolanin, et al.	
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	8	US- 2001/0000513 A1	04/26/2001	Purchase, JR. et al.	
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	11	US- 5,318,964	06/07/1994	Broadhurst, et al.	
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	FOREIGN PATENT DOCUMENT			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
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## NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>6</sup>
	87	J. NEMUNAITIS, et al., "Combined Analysis of Studies of the Effects of the Matrix Metalloproteinase Inhibitor Marimastat on Serum Tumor Markers in Advanced Cancer: Selection of a Biologically Active and Tolerable Dose for Longer-term Studies", <u>Clinical Cancer Research</u> , Vol. 4, pp. 1101-1109 (1998).	
	88	A. E. YU, et al., "Matrix Metalloproteinases – Novel Targets for Directed Cancer Therapy", <u>Drugs and Aging</u> , Vol. 11, No. 3, pp. 229 – 244 (1997).	
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	91	B. HENDERSON, et al., "Design of Inhibitors of Articular Cartilage Destruction", <u>Drugs of the Future</u> , Vol. 15, No. 5, pp. 495 – 508 (1990).	
	92	A. F. CHAMBERS, et al., "Changing Views of the Role of Matrix Metalloproteinases in Metastasis", <u>Journal of the National Cancer Institute</u> , Vol. 89, No. 17, pp. 1260 – 1270 (1997).	
	93	R. REICH, et al., "Effects of Inhibitors of Plasminogen Activator, Serine Proteinases, and Collagenase IV on the Invasion of Basement Membranes by Metastatic Cells" <u>Cancer Research</u> , Vol. 48, pp. 3307 – 3312 (1988).	
	94	T. G. WOLFSBERG, et al., "ADAM, a Novel Family of Membrane Proteins Containing A Disintegrin And Metalloprotease Domain: Multipotential Functions in Cell-Cell and Cell-Matrix Interactions", <u>The Journal of Cell Biology</u> , Vol. 131, No. 2, pp. 275 – 278 (1995).	
	95	H. S. RASMUSSEN, et al., "Matrix Metalloproteinase Inhibition as a Novel Anticancer Strategy: A Review with Special Focus on Batimastat and Marimastat", <u>Pharmacol. Ther.</u> , Vol. 75, No. 1, pp. 69 – 75 (1997).	

	96	D. E. MULLINS, et al., "The Role of Proteinases in Cellular Invasiveness", <u>Biochimica et Biophysica Acta.</u> , Vol. 695, pp. 177 – 214 (1983).	
	97	S. R. BRAMHALL, "The Matrix Metalloproteinases and Their Inhibitors in Pancreatic Cancer", <u>International Journal of Pancreatology</u> , Vol. 21, No. 1, pp. 1 – 12 (1997).	
	98	J. R. MORPHY, et al. "Matrix Metalloproteinase Inhibitors: Current Status", <u>Current Medicinal Chemistry</u> , Vol. 2, pp. 743 – 762 (1995).	
EXAMINER		DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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